

REMARKS

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

I. CLAIM STATUS AND AMENDMENT

Claims 1-20 were pending in this application when last examined.

Claims 1-4 were examined on the merits and stand rejected.

Claims 5-20 were withdrawn as non-elected subject matter.

Claims 1 and 2 are amended herein to clarify the claimed invention. New claims 21-23 are added. Support for these amendments may be found in the claims as originally filed and in the Specification as follows. Support for the amendment to claim 1 may be found in the Specification on page 18, lines 30-31, and page 27, lines 13-14. Support for the amendment to claim 2 may be found in the Specification on page 18, line 31. New claims 21-23 are supported in the Specification on page 30, lines 8-34, and correspond to cancelled claims 9-11, respectively.

Claims 5-20 are cancelled herein without prejudice or disclaimer thereto.

No new matter has been added.

II. NOVELTY REJECTION

On page 2 of the Office Action, claims 1, 3 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 0172290.

Applicants respectfully traverse this rejection as applied to the amended claims.

Applicants note that the claim 1 is amended herein to recite:

1. (Currently amended) A sustained-release preparation comprising (1) a dipeptidyl peptidase IV inhibitor and (2) a hydrophilic polymer selected from hydroxypropyl cellulose and hydroxypropylmethyl cellulose, wherein the content of the hydrophilic polymer in the preparation is 5-90 wt%.

Thus, the content of the content of the hydrophilic polymer in the preparation cannot be less than 5 wt%, which reflects the subject matter of non-rejected claim 2 and, in addition, the

subject matter of claim 1 is further limited to a specific range, based on page 18 of the Specification, lines 30-31.

Because claim 1 is so amended, Applicants respectfully submit that the ground of this anticipation rejection is untenable, as applied to the amended claims, and should therefore be withdrawn.

III. OBVIOUSNESS REJECTION

On pages 3-4 of the Office Action, claims 1-4 are rejected under 35 USC 103(a) as being unpatentable over WO 0172290.

Applicants respectfully traverse this rejection as applied to the amended claims.

The claimed invention can provide a sustained preparation by using a dipeptidyl peptidase IV inhibitor and a hydrophilic polymer selected from hydroxypropyl cellulose and hydroxypropylmethyl cellulose (claim 1 as amended herein), which preparation shows a drug dissolution rate from the preparation at 30 min after the start of the test of less than 85% as defined in the Specification on page 14, lines 29 - page 15, line 3. In the claimed invention, "sustained-release" means a drug dissolution rate from a preparation at 30 min after the start of the test of less than 85%.

DPP-IV inhibitors are useful as a therapeutic drug for diabetes. Further, taking into account the following situations (Specification page 1, lines 9-13; page 1, line 17 - page 2, line 2):

- 1) a DPP-IV inhibitor potentiates the vasodilating action of substance P;
 - 2) strong inhibition of DPP-IV activity in diabetic patients with concurrent chronic inflammation is considered to be unpreferable because it causes aggravation of inflammation;
 - 3) since GLP-1(9-36) amide, which is a metabolite due to DPP-IV of GLP-1 (glucagon-like peptide-1), has a hypoglycemic action, selective DPP-IV activity is important in glucose homeostasis; and
 - 4) the severity of depression and anxiety, which are side effects, correlates with decrease of serum DPP-IV activity in an interferon- α treatment of patients with hepatitis C,
- the present inventors have developed a sustained preparation which can control a drug dissolution rate from the preparation at 30 min after the start of the test to be less than 85%.
- WO'290 does not evince an awareness of the problem to be solved by the claimed invention, namely, that strong inhibition of DPP-IV activity due to a DPP-IV inhibitor is not necessarily preferable for a living organism; further, WO'290 does not show an understanding of the role of

controlled release of a DPP-IV inhibitor in relation to this problem. Moreover, WO'290 does not teach hydroxypropyl cellulose and hydroxypropylmethyl cellulose as a hydrophilic polymer.

Hence, Applicants respectfully submit that one skilled in the pertinent art would find no reason in the teaching of WO'290 to modify its teachings in order to arrive at the claimed invention, nor could he reasonably expect success of the claimed preparation from WO'290.

Therefore, Applicants respectfully submit that the rejection is untenable as applied to the amended claims and should be withdrawn.

CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance and early notice to that effect is hereby requested.

If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

Respectfully submitted,

Yohko AKIYAMA et al.

/Jon T.

By **Self/**

Digitally signed by /Jon T. Self/
DN: cn=/Jon T. Self/, o=us,
email=jsself@wenderoth.com,
c=US
Date: 2010.08.17 13:12:41 -04'00'

Jon T. Self, Ph.D.
Registration No. 48,948
Attorney for Applicants

WMC/JTS/ats
Washington, D.C. 20005-1503
Telephone (202) 721-8200
Facsimile (202) 721-8250
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